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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,847	03/06/2002	Neal R. Cutler	CUTLER-06830	9631

7590 04/28/2005

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EXAMINER	
YEBASSA, DESTA LETTA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,847	CUTLER, NEAL R.	
	Examiner	Art Unit	
	Desta L. Yebassa	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *18-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment or remarks filed on 12/20/2004.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18 - 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 3 of U.S. Patent No. 6,685,951. Although the conflicting claims are not identical, they are not patentably distinct from each other. U.S. Patent No. 6,685,951 claims a methods of treating migraines by administering a spray of DHE sublingually which consists of one active ingredient and one or more inactive ingredients, wherein said active ingredients is dihydroergotamine. At the time the invention was made it would have been obvious to administer DHE is various form sublingually with various pharmaceutical excipients. One would be motivated to administer the DHE in various forms to provide the best mode of administration for the particular patient to achieve the same effective result of treating a migraine.

Therefore, Claims 18 – 23 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 3 of U.S. Patent No. 6,685,951.

Applicant's argument with respect to U.S. Patent No. 6,685,951 has been considered but found unpersuasive according to the reason stated above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-23 are remain rejected under 35 U.S.C. 102(b) as being anticipated by the Caruso (U. S Patent No. 6043244). Caruso teaches a method treating migraines wherein dihydroergotamine is administered with an antimigraine-potentiating amount of an NMDA receptor antagonist (Col. 3, lines 14-58). All modes of administration are contemplated by Caruso (Col. 6, lines 3-67', Col. 7, lines 1-31)). Specifically, sublingual administration is taught in the form of a tablet, drop or lozenge (Col. 6, lines 25-28). Sprays and pastes or gels are also taught by Caruso (Col. 6, lines 30-35, 63-65). The oral tablets further comprise additives such as calcium carbonate, calcium phosphate or kaolin (Col. 6, lines 18-24). Additional active agents may be added to the composition (Col. 8, lines 12-27). Caruso recites DHE and its pharmaceutically acceptable salts (Col. 3, lines 14-40). It is the position of the Examiner that any form of DHE, the salt or

the base would acceptable for the formulation of Caruso. Therefore, Caruso teaches all the limitations of the instant claims.

Claims 18-23 are also rejected under 35 U.S.C. 102(b) as being anticipated by the Peyman (U.S Patent No. 5,855,907). Peyman teaches a method of treatment with an anti-inflammatory compound, which is a steroid; preferably, the streriod is gluocorticoid (column 2, lines 55). A method of treatment of migraine comprising the topical administration of an opioid with combination of anti-inflammatory compounds include steroids, particularly glucocorticoids, for example, cortisol, cortisone, prednisolone, dexamethasone and the like (column 5, line 55-65).

Response to Arguments

Applicant's arguments or remarks filed on 01/03/05 have been fully considered but they are not persuasive.

Applicants argue that the prior art cannot anticipate the instant claims because the prior art does not teach co-formulation of dihydroergotamine with a steroid. The primary reference, Caruso, teaches the general method describe above. The secondary reference Peyman, teaches a method of treatment of migraine comprising anti-inflammatory compounds include steroids, particularly glucocorticoids, for example, cortisol, cortisone, prednisolone, dexamethasone etc. (column 5, lines 55-65).

It is the position of the examiner that the combination of the prior art reference is proper and the reference recited teaches the limitations of the instant claims. Therefore, for the reasons stated above, applicants' arguments are found unpersuasive and the prior art rejections are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-23 are remain rejected under 35 U.S.C. 103(a) as being unpatentable over Caruso. The teachings of Caruso are discussed above. Caruso does not specifically teach the base of DHE or that the formulations are fast dissolve formulations. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use any form of DHE is a method of treating migraines. It would also be obvious from the teachings of Caruso to formulate any method of delivering the DHE to a host, including fast dissolve formulations. One of ordinary skill in the art would have been motivated to do this to provide a method treating migraines that is effective and achieves the effect in a shod amount of time to bring quick and direct relief to the host.

Claims 18-23 are also rejected under 35 U.S.C. 103(a) as being anticipated by the Peyman (U.S Patent No. 5,855,907). Peyman teaches a method of treatment with an anti-inflammatory compound which is a steroid, preferably, the streriod is glucocorticoid (column 2, lines 55). A method of treatment of migraine comprising the topical administration of an opioid with combination of anti-inflammatory compounds include steroids, particularly glucocorticoids, for example, cortisol, cortisone, prednisolone, dexamethasone and the like9 column 5, line 55-65).

Response to Arguments

Applicants argue failure to make a prima facie case of obviousness, advances an improper obvious to try standard, and further argued an opinion and perfunctory, bald, conclusory statements.

It is the position of the examiner that the combination of the prior art reference is proper and the reference recited teaches the limitations of the instant claims. Caruso teaches the antimigraine drug DHE is one such drug that fits within the class of drugs claimed by Pather AND that would be suitable for oral/buccal/sublingual administration. Therefore, proper motivation exists to combine the references. The motivation to do so is to deliver a drug through the oral mucosa through a dosage form that facilitates absorption of the active agent, DHE, across the oral mucosa. Still further, the references are suggestive ' of a composition comprising an antimigraine agent and that incorporation of such an agent will achieve the expected results of delivering the agent to the oral mucosa. Therefore, the obvious to try argument is unpersuasive.

The Examiner is using only the knowledge of the two references cited herein.

The Examiner is not making mere bald, perfunctory, conclusory accusations to formulate the instant rejection. Again, the primary reference, Caruso, teaches the general method as describe above. The secondary reference Peyman, teaches a method of treatment of migraine comprising anti-inflammatory compounds include steroids, particularly glucocorticoids, for example, cortisol, cortisone, prednisolone, dexamethasone etc. (column 5, lines 55-65).

It is the position of the examiner that the combination of the prior art reference is proper and the reference recited teaches the limitations of the instant claims. Therefore, for the reasons stated above, applicants' arguments are found unpersuasive and the prior art rejections are maintained.

Correspondence

Any inquiry concerning this communication from the examiner should be directed to Desta L Yebassa whose telephone number is (571) 272-8511. The examiner can normally be reached on Mon.-Friday 8:30 - 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone Number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600